COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMUNICATION FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

WTO decisions regarding the EC hormones ban

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1. Introduction

The objective of this Communication is to examine the various possible options concerning the ban on the import of beef from animals which have been treated with hormone growth promoters.

The Commission stresses that this Communication deals only with the ban on the imports of beef from animals which have been treated with hormone growth promoters. The question of the ban on the use of such substances within the Community is not addressed by the WTO judgement which has given rise to the present problem.

The options discussed are interim measures addressing the present problem of timing due to the fact that the WTO decided that the Community should bring its measures in conformity with the provisions of the Sanitary and Phytosanitary Agreement (SPS) within a "reasonable period of time" that expires on the 13th of May 1999.

It also stresses that final decisions on the Community's policies on hormones can only be taken on a science base and therefore when the results of the risk assessment are available and that this Communication is intended, in particular, to deal with the situation in which the Community now finds itself, in the run-up to the end of the "reasonable period".

2. Background

On 13 February 1998 the Dispute Settlement Body (DSB) of the World Trade Organisation adopted the Appellate Body Report and the Panel Reports, as modified by the Appellate Body Report, regarding "EC Measures concerning meat and meat products (Hormones)". The Appellate Body recommended that "the DSB request the European Communities to bring the SPS measures found...to be inconsistent with the Sanitary and Phytosanitary Agreement into conformity with the obligations of the European Communities under that Agreement". The Community indicated that it

intended to fulfil its obligations under the WTO, and that it would require a reasonable period of time to do so.

The Appellate Body had found that the Community had provided "general studies which do indeed show the existence of a general risk of cancer; but they do not focus on and do not address the particular kind of risk here at stake - the carcinogenic or genotoxic potential of the residues of those hormones found in meat derived from cattle to which the hormones had been administered for growth promotion purposes...those general studies are in other words relevant but do not appear to be sufficiently specific to the case at hand."

The Dispute Settlement Understanding (DSU) foresees in its Article 21.1 that "Prompt compliance with recommendations or rulings of the DSB is essential...", but it also recognises that this may not be possible. In Article 21.3, therefore, it provides that "...If it is impracticable to comply immediately with the recommendations and rulings, the Member concerned shall have a reasonable period of time in which to do so. That period of time shall be agreed between the parties or, in the absence of agreement, decided by an Arbitrator. The guideline for the Arbitrator is laid down as fifteen months, but it is also provided that this period can be shorter or longer, depending upon the particular circumstances.

Following unsuccessful efforts to agree a reasonable period with the US and Canada, an Arbitrator was appointed to determine that reasonable period.

The Community indicated that its intention was to conduct hormone specific and residue specific risk assessment for all the 6 hormones in question, as clarified by the Appellate Body, and, in the light of the results, to review the measure. We indicated that the risk assessment would require some two years, followed by approximately 15 months for any legislative process, which would be by co-decision.

The US and Canada argued that the DSB had ruled that there was no human health basis to the ban, which should therefore be removed.

The Arbitrator recalled the following points:

- The panels and Appellate Body recommended that the Community bring its measures, which were found to be inconsistent with the SPS Agreement, into conformity with its WTO obligations.
- Although Article 19.1 of the DSU provides that the Panel or Appellate Body can suggest ways in which this decision can be implemented, they did not do so.
- The Appellate Body concluded that the EC provision was not based on a risk assessment in accordance with the provisions of the SPS Agreement.

The Arbitrator stated that commissioning of scientific studies or consultations with experts were not considerations pertinent to the determination of the reasonable period of time, and could not justify a period of time longer that the guideline laid down in Article 21.3 of the DSU. Regarding the legislative process, the Arbitrator stated that under current EC law, a proposal to repeal or modify the ban, both internally and externally, could be taken under Article 43 of the Treaty; but he was "mindful" that

when the Amsterdam Treaty enters into force (which at that time was considered likely to be as early as January 1999), co-decision will be necessary.

On that basis, the Arbitrator granted the Community a "reasonable period" of 15 months (from the adoption of the rulings and recommendations on 13 February last) to implement those rulings and recommendations - that is, **until 13 May 1999.**

In line with the intention indicated above, the Commission has initiated a complementary risk assessment last year. In order to improve and complement recent scientific evidence regarding the potential adverse effects on human health of hormone residues in meat, and at the same time respond to the criticism by the WTO Appellate Body concerning the scientific basis of the EC import ban, a number of new scientific studies were commissioned (see annex). Work on these started as early as February 1998. Final results from most of these projects are expected to become available in the course of 1999, while others will terminate only in 2000. Intermediate results are foreseen at an earlier stage for all projects.

Meanwhile, on the basis of data which has become available in recent years, and the final or interim results available from the new studies, the appropriate independent scientific committee (the Scientific Committee on Veterinary Matters relating to Public Health, SCVPH) has been requested to deliver an opinion before the end of April 1999, responding as far as possible to a number of questions intended to clarify what potential adverse effects may arise from residues in bovine meat and meat products, resulting from the use of the 6 hormones in question for growth promotion in cattle. It must be noted that the conclusions of the risk assessment may differ for each of the 6 substances and, therefore, the Community policy in each case may differ accordingly. In accordance with the rulings of the Appellate Body, the Commission's risk assessment will also take into account risk arising from difficulties of control, inspection and enforcement of the requirements of good veterinary practice.

If the SCVPH is unable to give a conclusive opinion in April, it will be requested to complete its opinion as soon as possible in the light of the new studies.

3. Community interest

The Community has two key interests which are relevant in this affair:

(a) It must ensure a high level of consumer health protection and it must ensure that an objective, transparent and reliable procedure is followed for the evaluation of the risk in question.

(b) It must respect its obligations under the WTO, including the SPS Agreement, *inter alia*, in light of its attachment to the dispute settlement procedures of the WTO and because it is in our interest that other members of the SPS do not erect artificial barriers against our exports.

The SPS Agreement, as clarified by the Appellate Body ruling taken as a whole, does not involve any conflict between these two objectives, as it is clear that signatories of the SPS retain the sovereign right to determine their own level of health protection,

provided that any trade restricting measures to enforce that chosen level of protection are reasonably supported by a risk assessment. But, in this specific case, the Community faces a difficult problem of timing, due to the fact that there is at present a ban in place on imports and, until a risk assessment is performed that also fulfils the requirements under the SPS Agreement, as clarified by the Appellate Body, it can neither be defended internationally nor easily concluded that it can be modified.

At this point in time it is not possible to estimate, with any degree of certainty, the time frame within which scientific advice of the SCVPH permitting the conclusion of a risk assessment will be available. The Community may, therefore, not be in a position to meet the 13 May deadline. It is against this background that this Communication has been prepared.

4. Implications of failing to bring our legislation into conformity by the end of the reasonable period

The DSU is clear that the preferred outcome is conformity by the end of the reasonable period. It nevertheless recognises that this may not always happen and provides two possible measures which are available to deal with a situation where conformity has not been achieved by then. One is compensation. Article 22.2 provides[1], *inter alia*, that if a member has not complied within the reasonable period of time that member should, if so requested, enter into negotiations with the complaining parties in order to agree temporary compensation. The other is withdrawal of concessions by the complaining parties. The level of the withdrawal of concessions and the sectors on which it falls is decided by the complaining parties, subject to a right of arbitration on the level of the withdrawal of concessions. Such suspension of concessions or other obligations shall only be applied until the measure found to be inconsistent has been removed or a mutually satisfactory solution has been found (Article 22.8 of the DSU).

5. Options available to the Community in the present situation

In order to prepare the possible situations which may apply from the end of April or early May when interim results of the Commission's risk assessment are expected and the "reasonable period" expires, the following options (which are not mutually exclusive) can be considered:

(1) The Commission could encourage the complainants to enter into negotiation on compensation. "Compensation" in this context means trade concessions and

[1] Article 22.2 of the DSU: "If the Member concerned fails to bring the measure found to be inconsistent with a covered agreement into compliance therewith or otherwise comply with the recommendation and rulings within the reasonable period of time determined pursuant to paragraph 3 of Article 21, such Member shall, if so requested, and no later than the expiry of the reasonable period of time, enter into negotiations with any party having invoked the dispute settlement procedures, with a view to developing mutually acceptable compensation. If no satisfactory compensation has been agreed within 20 days after the date of expiry of the reasonable period of time, any party having invoked the dispute settlement procedures may request authorization from the DSB to suspend the application to the Member concerned of concessions or other obligations under the covered agreements."

it is likely that, if the complainants are prepared to consider compensation, they will insist that all or most of it would be in the agricultural sector, as this is the sector which is affected by our ban. Compensation could include increased access to Community markets. The final position of the Community would be defined in light of the risk assessment.

(2) The Community could, in accordance with Article 5.7 of the SPS Agreement[2], provisionally, adopt sanitary measures "on the basis of available pertinent information". Such a measure would not change the substance of the present prohibition but only transform it into a provisional one and it should be accompanied by further efforts to obtain the additional information necessary. Preparation to take action, hereunder in accordance with Article 5.7, could be initiated already now.

(3) The Commission could propose to lift the ban on imports provided that a suitable labelling scheme could be introduced which enabled consumers to recognise the beef concerned and avoid it, if they so chose. Such a proposal could be prepared already now, but would be put in place depending on the interim results of the risk assessment and thereafter kept under review.

Community actions in this field will require full information and political involvement of the Council and the European Parliament. Early preparation of proposals for legislation under options (2) and (3), allowing the Commission to act on the basis of the interim results of the risk assessment, could permit the Community to act quickly also during the period of election and reconstitution of the European Parliament.

6. Advantages and disadvantages of these options

The advantage of **option (1)** is that it offers the prospect of acting in agreement with the complainants and hence allowing the scientific studies and the risk assessment to be concluded in a calm atmosphere, thus optimising the chances of the risk assessment being generally perceived as being correct and objective, both by our own citizens and by the complainants. If temporary compensation is agreed, it would have the advantages that we would have influence on the choice of sectors to be affected by tariff measures and that it could be terminated rapidly as soon as the Community had an adequate scientific basis to take a decision. The amount of compensation likely to be agreed with the complainants can be expected to be significant, but it would be the result of an agreement. In contrast, the Community's influence on a retaliatory measure would be limited to the right to challenge the amount in a WTO arbitration. We cannot, however, be certain that it will prove to be negotiable.

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[2] Article 5.7 of the SPS Agreement: "In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time."

Option (2) allows the Community to act, in accordance with Article 5.7 of the SPS Agreement, on the basis of "available pertinent evidence" whenever it may become available and thereby to reduce to a minimum the period during which the Community risks not being in conformity with its SPS obligations. "Available pertinent evidence" could be "scientific evidence coming from qualified and respected sources"[3] or relevant evidence arising from difficulties of control, inspection and enforcement[4]. Unfortunately, the complainants appear, in any case, ready to contest the view that transformation of the ban into a provisional measure could, against the background of this dispute, ever be regarded as bringing us into conformity with our obligations. Therefore, a damaging trade dispute is likely to emerge despite the strength of the Community's arguments.

Option (3) has the advantage that it would bring the Community as quickly as possible into a position where, in the eyes of all relevant parties, it was in conformity with its obligations. This would avoid the need to provide compensation or suffer loss of concessions and it would enhance the Community's own ability to insist on the strict application of WTO agreements by other countries. But this option has the disadvantage (depending on the preliminary results of the scientific studies which are now in progress) that it might involve allowing onto the market a product which, hitherto we have considered to pose a potential risk. This action would take place prior to completion of the further studies which are currently underway to determine the reality of that risk, a decision which subsequent scientific results might put into question. Moreover, it may prove difficult to design a suitable labelling scheme which would not be contested by the complainants in the WTO.

If the Community refrained from or failed to take appropriate legislative action as well as to negotiate compensations, the complainants will, in all likelihood, obtain authorisation to implement sanctions in the form of withdrawal of concessions. This situation , although arguably less conflictual than option (2), is, however, likely to deprive the Community of the possibility to influence the measures that will be taken by the complainants.

7. Options in a time perspective

The options presented above are not mutually exclusive. On the contrary, they can be situated in a scenario as follows:

- It is clear that the Community's final position on the prohibition can be established only after the definitive conclusion of the current risk assessment. The time likely to be needed to arrive at such a conclusion poses, however, a problem of managing the intermediary period.

- On the basis of current information, the Commission expects to dispose, towards the end of April or early May, of interim results of the risk assessment. It is likely that these results may not be sufficient for the Community to take a

[3] Appellate Body report, paragraph 194.
[4] Appellate Body report, paragraph 205.

position on the current prohibition. In that case, the risk assessment will be continued.

- In light of this, it appears that option (1), i.e. negotiations with the complainants concerning temporary compensations, should be pursued without further delay.

- It is possible that, by the end of April or early May, the interim conclusions of the risk assessment will allow a fundamental re-evaluation of the situation; but it is also possible that it will prove necessary to await the definitive results of the risk assessment. In this last case, payment of temporary compensations would have to be made until such definitive results of the risk assessment become available and a definitive decision is taken.

- At any moment, the situation could be re-examined in terms of the three options mentioned in paragraph 5.

8. Conclusion

The Commission invites the Council and the European Parliament to urgently consider the options presented as well as their articulation over time with a view to determine their implementation up to and during the interim period.

In any case, the Commission will initiate preliminary discussions with the complaining parties in order to further evaluate the merits of the different options, and in particular will explore the feasibility of compensation.

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The study programme initiated by the European Commission on six hormones used for animal growth promotion

The European Commission has approved and financed a number of research projects on potential adverse human health effects arising from the use of the six hormones estradiol-17β, progesterone, testoterone, zeranol, trenbolone acetate and melengestrol acetate and their metabolites for growth promotion purposes. Final results from most of these studies are expected to become available in the course of 1999, while some projects will be finished in 2000. Intermediate results are foreseen at an earlier stage for all studies. The studies are the following:

One study is analysing the potential genotoxicity of a metabolite of oestradiol 17β in bovine meat and evaluating the potential health risks to consumers from the relevant residues in meat.

One study is analysing the potential genotoxicity and mutagenicity of the parent compounds trenbolone acetate and zeranol, and some of their metabolites. Residues extracted from bovine meat will be used to perform *in vitro* and *in vivo* studies. This project will also evaluate the potential risks to human health from the presence of residues of these two hormones in meat.

One study is a comprehensive study of the potentially genotoxic metabolites of oestradiol 17β and the potential risks of cancer to consumers arising from such residues in meat. The potential risks from misuse or failure to observe good veterinary practice in the administration of oestradiol 17β will also be examined. This study is a collaboration of several research experts and laboratories, in view of the wide range of the experimental research involved.

One study will concentrate on melengestrol acetate, but will also search for other metabolites of trenbolone acetate and zeranol not covered by the second project mentioned above. The carcinogenicity and genotoxicity of the parent compounds and their metabolites will be tested *in vitro* and *in vivo*. Potential risks to human health from residues in meat will be evaluated.

One study is focusing on the gene expression of low levels of zeranol in order to assess potential adverse human health effects of this substance.

A number of studies have been initiated to provide residue-specific results, while potential risks to human health resulting from misuse and failure to respect good veterinary practice in the administration of all six hormones are also studied. This covers possible misuse and disregard of good veterinary practice.

Furthermore, a number of studies on the direct and indirect effects on the environment and wildlife (such as degradation kinectics, presence in the environment, effects on animals) and the implications for human health have been

initiated. An epidemiological study on potential adverse endocrine effects is also under way.

In total, 17 research studies related to hormones have been initiated by the Commission.

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